

**REMARKS/ARGUMENTS**

Claims 1-2 and 4-11 are pending in the present application.

***Rejection of Claims 1, 2, and 4-11 Under 35 U.S.C. § 103(a)***

The Examiner has rejected claims 1-2 and 4-11 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,562,629 to Lin et al. Applicants traverse this rejection.

Contrary to the Examiner's assertion, Lin does not teach or suggest the use of balsalazide for the treatment irritable bowel syndrome (IBS). Moreover, Lin does not provide a reasonable expectation of success in using balsalazide to treat IBS in a human subject. At best, Lin suggests that 5-amino salicylic acid (5-ASA) compounds including balsalazide may be used to treat small intestinal bacterial overgrowth (SIBO).

The Examiner cites col. 18 lines 4-21 of Lin, which states that 4 and 5 ASA compounds could be used to "at least partially eradicate the SIBO condition." Balsalazide is listed in line 21 as one among many other aminosalicylate compounds that may be suitable. Nowhere in this section or in the remainder of the issued patent is balsalazide taught for the treatment of IBS.

The non-obviousness of the presently claimed subject matter is supported by unexpected results. Lin merely lists balsalazide as one among many other 4- and 5-ASA compounds that may be suitable for the use in treatment of any one of a number of diseases and disorders, including partially eradicating the SIBO condition, but does not suggest that balsalazide offers any particular benefit over the other compounds in the list. Nor does the specification teach which of the various compounds would be effective against which of the disclosed diseases and disorders. One of ordinary skill in the art knows that the disclosed molecules have different physical, chemical and therapeutic properties and would not expect all of these compounds to effectively treat all of the diseases and disorders disclosed. However, the specification provides no guidance as to which compounds should be used for treating each of the various diseases and disorders.

As stated on pages 5 and 6 of the present specification, the inventor discovered that treatment of patients with non infectious bowel disorders with 5-ASA compounds such as mesalazine and olsalazine or with 4-ASA compounds such as 4-aminosalicylic acid, whether alone

or in combination with 5ASA compounds, whilst capable of suppressing symptoms in most patients with diarrhea-predominant IBS symptoms may be even more effective when balsalazide is administered alone or in combination. From clinical experience, it has been found by the inventor that balsalazide is much more powerful at suppressing the symptoms of diarrhea-predominant irritable bowel syndrome than the other 4-ASA and 5-ASA compounds that have been used. Balsalazide is better than mesalazine (5-ASA) in controlling and may inhibit even more powerfully the symptoms of diarrhoea-predominant IBS and associated conditions. This is unexpected; it was not expected that balsalazide would be capable of treating diarrhea-predominant IBS as it is a very different molecule to the conventional 4-ASA and 5-ASA compounds. Balsalazide and its sodium salt are composed of a 5-amino salicylic acid joined to an unusually long chain, 4-amino benzoyl-b-alanine (4-ABA). It is therefore a much larger molecule and does not belong to the same molecular shape as mesalazine or olsalazine. The inventor found that balsalazide can substantially inhibit the symptoms of diarrhoea in patients with diarrhoea-predominant IBS. It is thought that this is due to a large extent to the properties of the unique 'inactive carrier' side chain (4-ABA). It is noted that the side chain together with the 5-ASA potentiates inhibition of gas production, cramping, fluid secretion, and mucus production. It appears the large side chain apart from the salicylate component is effective in treating diarrhoea.

**REMARKS**

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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